K041310

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stryker

Endoscopy

SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name

Classification Name:	Fastener, Fixation, Non-degradable, Soft Tissue 21 CFR §888.3040, Class II
Common and Usual Name:	Suture Anchor (MBI)
Proprietary Name:	Stryker Wedge Suture Anchor System

Predicate Device

Stryker Wedge Suture Anchor System (#K983557), currently marketed by Stryker Endoscopy (San Jose, CA).

Summary

This summary of Special 510(k) safety and effectiveness is being submitted in accordance with requirements of SMDA 1990.

The line extension of the Stryker Wedge Suture Anchor System is intended for use in providing a means for securing soft tissue to bone using suture. The line extension of the Stryker Wedge Suture Anchor System consists of a titanium alloy (Ti 6Al 4V ELI) screw-in type anchor pre-threaded with non-absorbable braided polyethylene surgical suture, and pre-assembled on a disposable inserter.

The line extension of the Stryker Wedge Suture Anchor System will be provided sterile for single-use (ASTM 4169). The device line extension will be sterilized by Ethylene Oxide (ANSI/AAMI/ISO 11135), including limits for Ethylene Oxide residuals and validated to a sterility assurance level (SAL) of 10^{-6}. The device is biocompatible per ISO-10993-1 and G95-1. The line extension of the Stryker Wedge Suture Anchor System is substantially equivalent in material of construction, overall design, intended use, and safety and efficacy to the predicate device. The subject device was shown to have substantially equivalent performance when compared to the predicate device.

The line extension of the Stryker Wedge Suture Anchor System is considered substantially equivalent to the Stryker Wedge Suture Anchor System (#K983557).

Contact:

Melissa Murphy
Regulatory Representative
Stryker Endoscopy
5900 Optical Court
San Jose, CA 95138
(408) 754-2148

Date: May 6, 2004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 4 2004

Ms. Melissa Murphy
Regulatory Representative
Stryker Endoscopy
5900 Optical Court
San Jose, California 95138

Re: K041310
Trade/Device Name: Stryker Wedge Suture Anchor System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: May 6, 2004
Received: May 17, 2004

Dear Ms. Murphy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041310

Device Name: Stryker Wedge Suture Anchor System

Indications For Use:

The intended use of the Stryker Wedge Suture Anchor System is for securing soft tissue to bone in such procedures as rotator cuff tear repair, Bankart lesion repair, and SLAP lesion repair in the shoulder, as well as Achilles tendon repair in the foot/ankle, medial collateral ligament repair in the knee, scapholunate ligament reconstruction in the hand/wrist, biceps tendon reattachment in the elbow, and bladder neck suspension in the pelvis. The suture anchor engages in bone so as to provide a stable, bony attachment site for the soft tissue. This device is intended to be used primarily in arthroscopic repairs, but is suitable in open procedures as well, and is intended for single-use only.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041310